Boston Biomedica, Inc.

NOV 2 4 2003

K032713

510(k) Summary

As required by 21 CFR Section 807.92(a), Boston Biomedica, Inc. is hereby providing a summary of the safety and effectiveness information contained in its 510(k) Notification for the Boston Biomedica, Inc. *Borrelia burgdorferi* IgM and IgG Western Blot Test Kit.

Submitters name: Boston Biomedica, Inc.

Address: 375 West Street
West Bridgewater, MA 02379

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Preparation Date: August 29, 2003

Name of the device: Boston Biomedica, Inc. *Borrelia Burgdorferi* IgM and IgG Western Blot Test Kit

Common name: *In Vitro* Diagnostic test for the detection of IgM and IgG antibodies to *Borrelia burgdorferi* in human serum.

Classification name: None available

Predicate Device: MarDx Lyme Disease (IgG) Marblot Strip Test System
Trinity Biotech, Inc.
Carlsbad, CA
510(k) Number: (K950829)

Boston
Biomedica,
Inc.

Description of the device:

The Boston Biomedica, Inc. (BBI) *Borrelia burgdorferi* IgM and IgG Western Blot Test Kit is an *in vitro* qualitative assay for the detection of IgM and IgG antibodies to *Borrelia burgdorferi* in human serum. This device is composed of the reagents, controls and test strips intended for use in Western blot testing of human serum samples for the presence of IgM and/or IgG antibodies to *B. burgdorferi.* The device is similar in composition to the previously approved BBI Biotech Research Laboratories *Borrelia burgdorferi* IgM Western Blot Test Kit. The kit also includes Blot Reading Guides, report forms and a Package Insert.

Intended use of the device:

The Boston Biomedica, Inc. (BBI) *Borrelia burgdorferi* IgM and IgG Western Blot Test Kit is intended for use in testing human serum samples that have been found positive or equivocal using an enzyme immunoassay (EIA) or immunofluorescence assay (IFA) test procedure for *B. burgdorferi* antibodies. Positive results from this Western blot assay are supportive evidence of infection with *B. burgdorferi,* the causative agent of Lyme disease

Summary of the technological characteristics of device compared to the predicate devices:

The Boston Biomedica, Inc. (BBI) *Borrelia burgdorferi* IgM and IgG Western Blot Test Kit uses the same Western blot technology as the predicate device. The BBI kit differs from the Marblot predicate device primarily in the strains of *B. burgdorferi* that are used, the type of initial antigen preparation, the requirement for a pre-wetting step, the length of incubation times, the standardization of substrate incubation, the method used to identify the bands of interest and the run acceptance criteria. In addition, the BBI *Borrelia burgdorferi* IgM and IgG Western Blot Test Kit contains all the reagents needed to perform both IgM and IgG determinations. These differences do not affect the safety or effectiveness of the device.

Summary of the clinical performance data:

The BBI *B. burgdorferi* IgM and IgG Western Blot Test Kit was evaluated using samples from patients who were culture-positive for *B. burgdorferi,* samples that had tested IgG EIA positive, the CDC Lyme panel, a commercially available panel of Lyme positive samples (PTL202), serum samples from random blood donors from Lyme endemic and non-endemic regions, and with samples from patients with ten other infectious diseases and conditions such as syphilis, rheumatoid arthritis, and systemic lupus erythematosus. The applicant device performance was compared with that of the predicate device for culture-positive samples, EIA positive samples, and PTL202.

Prepared by: Patricia E. Garrett, Ph.D.
Sr. Vice President, Science and Technology
Boston Biomedica, Inc.

BBI
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Patricia E. Garrett, Ph.D.
Senior Vice President, Science and Technology
Boston Biomedica, Inc.
375 West Street
W Bridgewater, MA 02379

Re: k032713
Trade/Device Name: Boston Biomedica, Inc. (BBI) *Borrelia burgdorferi* IgM and IgG Western Blot Kit
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema Pallidum Treponemal Test Reagents
Regulatory Class: Class II
Product Code: LSR
Dated: August 29, 2003
Received: September 4, 2003

Dear Dr. Garrett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032713

Device Name: Boston Biomedica, Inc. (BBI) *Borrelia burgdorferi* IgM and IgG Western Blot Kit

Indications For Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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